UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO CAROLYN LEWIS, et al. v. ETHICON, INC. Case No. 2:12-CV-04301	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

The deposition of BRUCE A. ROSENZWEIG, M.D., called for examination, taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before JULIANA F. ZAJICEK, CSR No. 84-2604, a Certified Shorthand Reporter of said State of Illinois, at the offices of Wexler Wallace, Suite 3300, 55 West Monroe Street, Chicago, Illinois, on November 4, 2013, at 9:00 a.m.

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REPORTED BY: JULIANA F. ZAJICEK, CSR No. 84-2604.

(WHEREUPON, the witness was duly sworn.)

BRUCE A. ROSENZWEIG, M.D.,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MS. JONES:

Q. Doctor, would you state your name and address for us please, sir?

A. Bruce Alan Rosenzweig. My professional address is 1725 West Harrison Street, Suite 358, Chicago, Illinois 60612.

Q. And, Doctor, you are an obstetrician/gynecologist by training?

A. That is correct.

Q. And do I understand correctly that you are in private practice, in the private practice of medicine here in Chicago now?

A. That is correct.

Q. How long have you been in private practice?

A. Well, I -- I started here in Chicago at the University of Illinois in 1998, I moved to Mercy Hospital where I was in more of a private practice than an academic practice, then I moved

time and the time that you started working in this litigation?

A. I -- I know I looked at a lot of patent documents. I don't remember specifically if the patent infringement case I was working on I saw 510(k) documents. So, I don't want to say yes at that point, which was also about six or seven years ago.

Q. Have you ever prepared clinical expert reports?

A. No, I have not.

Q. Have you ever prepared design history files?

A. No, I have not.

Q. Have you ever prepared DFMEAs?

A. No, I have not.

Q. Have you ever prepared IFUs?

A. Well, I did work with Gish Biomedical to get the information that they needed to put in the amnioinfusion catheter IFU.

Q. Did you actually draft the IFU?

A. No, I did not. I worked as a consultant on that.

Q. Have you ever drafted an IFU?

A. No, I have not.

Q. Have you ever drafted a patient brochure?

A. I worked on the amnioinfusion catheter brochures, yes.

Q. Other than your working as a consultant with Gish on the IFU and patient brochure on the IFU, have you ever had any other experience either as a consultant or drafting an IFU or patient brochure?

A. Yes. I was on EMPI's scientific advisory committee in the mid-'90s and I know we worked on various documents like that. I can't --

Q. You were on whose scientific advisory committee?

A. EMPI. It is a company in Minnesota that makes an electrical stimulator for the treatment of stress incontinence and urge incontinence.

Q. And so your role there was?

A. An adviser to -- at that point they were working on doing a prospective randomized controlled trial because the insurance companies were looking at this technique as experimental, and so they needed to get some data in the literature to show that it wasn't experimental.

Q. Have you ever prepared any risk

management reports?

A. No, ma'am. Well, risk management as far as medical -- medical products, right?

Q. Right.

A. Okay. Good.

Q. Not in terms of your hospital --

A. Patients, doctors, right.

Q. -- services and patients and all of that.

Have you ever been an employee or consultant to the FDA?

A. No, I have not.

Q. Have you ever served on an FDA advisory committee meeting?

A. No, I have not.

Q. Have you ever corresponded with the FDA with respect to your opinions on anything about a medical device?

A. No, I have not.

Q. Have you ever shared with the FDA any of your opinions that you have included within your reports marked as Exhibits 2 and 3 here?

A. No, I have not.

Q. Have you ever published these opinions in any other form other than in this report marked

as Exhibit 2 and 3?

A. I think there is some of the I'll call it factual information in a presentation that I gave this year about polypropylene degradation and stuff like that, but that would be the only thing.

Q. That would be in one of the --

A. Slide decks, yes.

Q. -- slide decks?

A. Yes.

Q. Again, we'll come back to those --

A. Excellent.

Q. -- in just a second.

You don't have any background in polymer chemistry, do you?

A. No, ma'am.

Q. You don't consider yourself to be a biomaterial specialist?

A. I have not studied biomaterials, nor do I have an advanced degree in biomaterials.

Q. And I take it it's true that you've never done any bench research or lab research with respect to polypropylene?

A. Not to polypropylene.

Q. Am I correct that you have never advised the FDA of any of your opinions that you've

device report to either the FDA or to Ethicon?

A. Yes. I filled out the paperwork for those.

Q. And this was in when?

A. 2004, 2005, 2006.

Q. On how many occasions?

A. I'm going to say at the most five.

Q. Were these implants that you had implanted?

A. There was one case that I remember that I implanted that had an erosion, and I'm pretty sure I filled out the paperwork with the rep on that case, but the other ones were ones that were sent to me.

Q. All right. Now, my initial question to you was degradation --

A. That is correct.

Q. -- not erosion. So my -- let me go back and make sure that we are on the same page.

Did you report to anyone a finding of erosion -- of degradation in 2004 or 2005?

A. No, ma'am.

Q. Have you ever reported that to anyone?

A. No, ma'am.

Q. Have you ever done any type of

pathological analysis on a removed TVT or implant?

A. Myself?

Q. Yes, sir.

A. No, ma'am.

Q. Have you ever ordered that one be done?

A. I send the explants that I do down to pathology, so I guess that would be considered ordering.

Q. And they would do whatever their normal pathological process or procedure is in terms and then those records would just be included within the medical records?

A. That is correct.

Q. Other than that, have you been engaged in any type of analysis of polypropylene?

A. No, ma'am.

Q. Have you ever reported to anyone that you have seen or observed any particle loss from polypropylene?

A. Except to the patient, just to the patient.

Q. Have you ever reported that to the FDA?

A. No, ma'am.

Q. Have you ever reported it to Ethicon?

A. No, ma'am.

A. Those two in specific, no. Just those two being representative of the body of retropubic and obturator TVTs.

MS. JONES: Let's just take a break and we'll do that and have lunch, unless you all are all assuming -- yes, it is one o'clock. You all are ready for it.

MR. CARTMELL: Okay.

(WHEREUPON, a recess was had from 12:58 to 1:38 p.m.)

BY MS. JONES:

Q. I'm going to quickly go through a series of things just to clean up my notes to make sure I've asked the question.

Other than Exhibit 6 which is your PowerPoint, you never published anything on polypropylene, is that correct?

A. That is correct.

Q. You never published anything on the degradation of polypropylene, is that correct?

A. That is correct.

Q. You've never done -- never published anything about the porosity of mesh, correct?

A. That is correct.

Q. You never published anything on the

cytotoxicity of mesh, correct?

A. That is correct.

Q. You never published anything on fibrotic bridging, correct?

A. That is correct.

Q. You never published anything on contracture, correct?

A. That is correct.

Q. You are not a pathologist?

A. I have not done a residency program in pathology. I am not boarded by the American Pathological Association.

Q. You are not a polymer chemist?

A. That is correct.

Q. Not an organic chemist?

A. That is correct.

Q. Not a toxicologist?

A. That is correct.

Q. You've done no research and development with respect to polypropylene?

A. That is correct.

Q. You've never done any examination of a biomaterial to evaluate tensile strength, for example?

A. A biomaterial, we did a study on -- on

Q. And that information that you've presented based upon your findings at that time, to the extent that it was based upon any confidential documents would have been based upon either Bard or AMS documents, correct?

A. That was not related to any confidential documents.

Q. So there wasn't any confidentiality associated then with it, was there?

A. Well, from -- quite frankly, I err on the side of I don't know what I can or can't talk about in this and I prefer not to talk about it so that I don't have any problems later on.

Q. Fair enough.

A. Okay.

Q. I'm going to skip around a little bit, so just bear with me to get through with some of this stuff.

You've never performed any pathological testing on sutures, is that correct?

A. I did a pathology rotation when I was a student and also during residency. We might have looked at sutures under the microscope. But are you talking about doing any kind of pathological stuff?

Q. Analysis or study or --
A. No.
Q. And the same would be true with respect to mesh or polypropylene in general?
A. That is correct.
Q. You've never dried or cleaned mesh for any pathological analysis, correct?
A. That is correct.
Q. You have never sputter coated an explanted mesh?
A. Have I explanted mesh, yes, I have.
Q. No. Have you sputter coated?
A. Sputter coated.
MR. CARTMELL: It sounds funny.
BY THE WITNESS:
A. I have explanted mesh. I really do not remember ever sputter coating the explanted mesh.
BY MS. JONES:
Q. Have you ever done any differential scanning calorimetry?
A. I don't even think I can pronounce that.
Q. Huh?
A. No, I have not.
Q. How about thermogravimetric analysis?
A. No.

Q. How about compliance testing to determine mesh density?
A. No.
Q. How about any type of oxidative degradation testing?
A. No.
Q. Any type of molecular weight determination?
A. No.
Q. Any type of uniaxial testing?
A. Uniaxial tension testing?
Q. Testing.
A. Uniaxial would be a tensioning test?
Q. Yes.
A. Okay. No.
Q. Pore size measurement either with or without load?
A. No.
Q. Mechanical testing?
A. No.
Q. Chemical analysis?
A. Of what?
Q. Of either polypropylene mesh or poly --
A. Oh, okay. I mean, I've done a lot of chemical analysis back when I was in chemistry, but

not of mesh.

Q. Not of mesh, not of polypropylene?

A. That is correct.

Q. No toxicity or cytotoxicity testing of polypropylene or mesh?

A. That is correct.

Q. Have you ever read the FDA regulations pertaining to polypropylene meshes?

A. The FDA regulations regarding what?

Q. Polypropylene meshes?

A. Regarding what?

Q. Anything.

A. The -- quite frankly, that is such a broad question, I don't know how to answer that question.

Q. Well, when is the last time you reviewed the FDA regulations on medical devices?

A. For what?

Q. Just for any purpose.

A. No, no, I mean for clearing devices, for the various, you know, components of the device, like the IFU? That's why I'm having a little bit of problems.

Q. What I'm trying to find out is to what extent you are going to claim that you are an

you would, why it is that you as a surgeon who performs pelvic surgery has expertise related to what warnings and adverse reactions need to be in an IFU?

A. Well, I have experience using medical devices, I have experience determining whether or not I'm going to use medical devices in my practice, I have experience determining if a particular medical device is useful for a specific patient and then counseling the patient on those individual -- on the risks associated with a particular medical device so that that patient can determine if she wants to have a medical device either implanted or used to treat her condition.

MR. CARTMELL: All right. Thanks. That's all I have.

FURTHER EXAMINATION

BY MS. JONES:

Q. Doctor, you would agree that any other urogynecologist or specialist in female pelvic surgery or treating stress urinary incontinence would have similar expertise, correct?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. I think that doctors have -- that are

using the IFU, using it to decide if they are going to keep it in their -- use a device in their practice to determine if an individual patient that device is useful for and then counseling the patient on the use of that device, the risks and benefits associated with it, I would say that that would qualify them as an expert in IFUs.

MS. JONES: Thank you. That's all I have.

(Time Noted: 4:43 p.m.)

FURTHER DEPONENT SAITH NAUGHT.